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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/196,154	11/16/1995	PHILIP O. LIVINGSTON	43016-A-PCT-	5954

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EXAMINER
HUNT, JENNIFER ELIZABETH

ART UNIT	PAPER NUMBER
1642	30

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/199,154	Livingston
Examiner	**Art Unit**
Jennifer Hunt	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *97, 101-111, and 113-118* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *97, 101-111, and 113-118* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Acknowledgment is made of applicant's cancellation of claims 98 and 99 Claims 97, 101-111 and 113-118 are pending in the application and considered herein.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim Rejections Withdrawn

3. The rejection of claims 97-99, 101-111, 113, and 115-118 under 35 U.S.C. 103(a) as being unpatentable over Livingston et al. (Cancer Research, 149:7045-7050, 1989) in view of Ritter et al. (Seminars in Cancer Biology, 2:401-409, 1991), Liane et al (Journal of Biological Chemistry, 249(14):4460-4466, 1974), Livingston et al. (U.S. Patent No. 5,102,663), Ritter et al. (Immunobiol, 182:32-43, 1990), Kensil et al.(The Journal of Immunology, 146(2):431-437, 1991), and Marciani et al. (Vaccine, 9:89-96, 1991) and Uemura et al (J Biochem, 79(6):1253-1261, 1976) is withdrawn in light of the amendments thereto.

4. The rejection of claim 114 under 35 U.S.C. 103(a) as being unpatentable over Livingston et al. (Cancer Research), Ritter et al. (Cancer Biology, 1991), Liane et al (Journal of Biological Chemistry, 249(14):4460-4466, 1974), Livingston et al. (U.S. Patent No. 5,102,663), Ritter et al. (1990), Kensil et al, and Marciani et al., and Uemura et al (J Biochem, 79(6):1253-1261, 1976)

as applied to claims 97-99, 101-111, 113, and 115-118 above and further in view of Irie et al. (U.S. Patent Nol 4,557,931) is withdrawn in light of the amendments thereto.

Objections or Rejections Maintained

Specification

5. The prior objection to the disclosure is maintained for the reasons as set forth in the Office Action mailed 6/19/98 (see Paper No. 16).

Applicants submit they will provide a new Figure 6B to overcome the rejection when the case is in condition for allowance. Until applicants submit a proper Figure said objection is maintained.

Double Patenting

6. The rejection of claims 97, 101-111 and 113-118 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78-92 and 94-99 of copending Application No. 08/477,097 for reasons made of record in paper #20, mailed 10-6-1999, and paper #22, mailed 6-27-2000 is maintained for reasons of record, as applicant argues only that the rejection should be withdrawn if the claims are found allowable.

7. The rejection of claims 97, 101-111 and 113-118 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims 78-93, and 95-100 of application No 08/475,084 for reasons made of record in paper #20, mailed 10-6-1999, and paper #22, mailed 6-27-2000 is maintained for reasons of record, as applicant argues only that the rejection should be withdrawn if the claims are found allowable.

8. The rejection of claims 97, 101-111, and 113-118 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 109-122 of copending Application No. 08/477,147. Although the claims are not identical, they are not patentably distinct from each other because the claims of 08/477,147 also encompass the same composition as that which is instantly claimed (a conjugate comprising a ganglioside derivative with an altered ceramide portion conjugated to an immunogenic protein based carrier, a saponin, and a pharmaceutically acceptable carrier, and a method of treatment using such,) is maintained for reasons of record, as applicant argues only that the rejection should be withdrawn if the claims are found allowable.

New Grounds of Rejection

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 97, 101-111, and 113-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to a C-4 carbon of the sphingosine base of the ceramide portion of the ganglioside derivative, which clearly is drawn to the starting compounds from which the claimed conjugate is formed, and then later the claim recites that the C-4 carbon is present in a CH_2 group, which clearly refers to the final formed conjugate. Thus it is not clear of the C-4 carbon referred to is part of the starting materials (as part of the ganglioside derivative) or part of the ultimate conjugate product. Amending the claim so that the C-4 carbon is consistently referred to in terms of it's position in the ultimate conjugate would likely bring favorable consideration.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 97, 101-111, and 113-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims now recite that the C-4 carbon is present in a CH_2 group. Applicant does not cite a portion of the specification which provides support for this limitation. The claims appear to find support of this specific

configuration in Figure 1. However the claim as recited encompasses molecules other than that depicted in Figure 1 (Figure 1 is a species of the genus of molecules claimed), and it is not clear that the specification as filed specifically contemplated the generic composition instantly claimed, which has the specific limitation that the C-4 carbon is present in a CH_2 group. Because there is no support in the specification for a the compound as instantly claimed, with a C-4 carbon present as part of a CH_2 group, this limitation is new matter, as it is different from the scope of any of the compounds initially contemplated. Limiting the claims to the compound of Figure 1, or making it clear where in the specification provides support for this specific limitation in terms of the generic claim will likely bring favorable consideration.

Status of Claims

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

June 30, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600